

## **Summary Report on Public Comments on the Objectives posted regarding Vaccine Safety Activities**

### **Process:**

In June 2004, Julie Gerberding, Director of the Centers for Disease Control and Prevention (CDC) requested that a diverse group of individuals be convened to review the vaccine safety monitoring and research activities at CDC. The meeting was a 2-day meeting in which participants engaged in frank and wide-ranging discussion of current programs and perceptions about the safety of immunization. In addition, the discussion emphasized a collective awareness that vaccine safety is a subject that requires much broader governmental and private involvement in keeping with the evolving characteristics of disease epidemiology, community expectations and expanding clinical and laboratory science.

The group of individuals was asked to review and discuss three objectives during their 2-day meeting. The purpose of providing objectives for the participants was to assist them in discussing the vaccine safety program at CDC on a broader level; therefore, they were not convening to discuss specific vaccine safety studies, the thimerosal issues, the recent IOM report or other more specific details of the vaccine safety program.

The individuals were asked to provide individual opinions on the following three objectives:

- 1) Review the structure, function, credibility, effectiveness, efficiency and support of CDC's vaccine safety program and assess how it can be maximized and sustained.
  - Assess the program's ability to detect emerging or rare adverse events.
  - Assess the capacity of the program to provide comprehensive monitoring of the growing number of vaccines.
- 2) Review the intramural and extramural collaborative activities of the vaccine safety program and determine their effectiveness and efficiency:
  - Assess additional steps CDC can institute to enhance coordination with other federal agencies and partners, including consumer and advocacy groups.
- 3) Determine the optimal organizational location for vaccine safety activities within the CDC to ensure scientific objectivity, transparency and oversight while at the same time ensuring that program priorities are appropriately established and are relevant to immunization program and stakeholder needs.

The group consisted of 17 individuals from a variety of professional organizations, advocacy groups, government advisory committees, and government agencies. In an

effort to create a balanced group of participants with complementary skill sets, diverse points of view, and general interest in vaccine safety issues while maintaining a size that would allow the meeting to be productive and manageable, the following guidelines were utilized to choose participants.

- Broad understanding and knowledge of risk assessment, risk management, and quality assurance
- Interest and or knowledge of vaccine safety issues
- Partners with diverse perspectives who work with CDC on vaccine safety issues{and research agenda}
- Partners with diverse perspectives who work with CDC in an advocacy role for public health issues and/or have engaged CDC in discussions on this issue
- Individuals who want credible vaccine safety information which include: health care providers, consumers, other federal agencies, industry, professional groups and others

After the meeting a summary report was prepared. The meeting participants reviewed and edited the report and it was then provided to the Director of CDC.

In an effort to obtain broader public input on the objectives posed to the meeting participants, the objectives, as well as the presentations presented at the meeting, were posted on the CDC website from August 12 until October 12, 2004 for public comment. Once the public comment period ended those comments received were reviewed using the following guidelines:

- If a comment or comments were submitted by an individual more than one, it was only counted once
- The comments relevant to the vaccine safety issues were included.
- Comments and questions that were not responsive to the objectives were not included, e.g. asking what type of vaccines is needed for travel to certain countries, personal stories of experiences with vaccines, specific questions regarding the flu vaccines and shortage issues, etc.
- Comments that were not specifically related to the objectives, but were related to vaccine safety were placed into “additional comments” section.
- Comments were listed by the frequency with which they were mentioned from most often to least often.

All public comments were considered important by CDC and were reviewed.

## **I. Comments regarding objectives posed to the Blue Ribbon Panel:**

### **406 public comments including congressional response**

## **II. Public comments:**

- 54** comments did not respond to the objectives and were not related to vaccine safety issues, e.g. many comments included personal stories about their experiences with vaccines, **2** asked specific questions about vaccines needed for international travel, **1** had concerns about the rabies vaccine and **21** had specific questions and comments regarding the influenza vaccine and shortage issues which vaccines are needed for international travel, and other issues.
- 3** comments were from organizations representing more than 1 individual
- 42** comments were duplicates

**Numbers in parenthesis after the comments represent the frequency, or number of times, this comment was mentioned.**

### **Public Comment Responses to objectives:**

***Objective 1: Review the structure, function, credibility, effectiveness, efficiency and support of CDC's vaccine safety program and assess how it can be maximized and sustained.***

***\*Assess the program's ability to detect emerging or rare adverse events.***

***\*Assess the capacity of the program to provide comprehensive monitoring of the growing number of vaccines.***

There is under-reporting of Adverse Events (AE) through the VAERS (Vaccine Adverse Events Reporting System) therefore the data is inaccurate (adverse events are not rare, they are just not reported) (58)

CDC has failed at tracking AE (34)

Access effectiveness of VAERS/improve the VAERS system/ need timely studies of AE (25)

Parents are unaware of how to report AE and physicians are not identifying and reporting these as AE. All healthcare providers giving immunizations need education as to appropriate identification and reporting of AE (21)

Develop long term studies to compare children who receive and those who do not receive vaccines to look at AE, especially chronic diseases such as diabetes. This would help to get at the efficacy and safety of vaccines (19)

Believe CDC is the authority and does a good job on vaccine safety (17)

CDC should mandate reporting of AE (4)

Need to label vaccines better to avoid mixing them up and be able to track AE via lot numbers (3)

Unsure if the vaccine safety program is able to detect rare or emerging AE (2)

CDC's ability to monitor and track is questionable

Need to move to rapid review of experimental vaccines to use in pandemic situation

Balance risk of harm with risk of morbidity/mortality

Controversy over vaccines is confusing and makes it difficult for parents to make a decision and have confidence in CDC's ability to detect emerging and/or rare AE.

***Objective 2: Review the intramural and extramural collaborative activities of the vaccine safety program and determine their effectiveness and efficiency.***

***\*Assess additional steps CDC can institute to enhance coordination with other federal agencies and partners, including consumer and advocacy groups.***

Collaborate by allowing independent scientists to have open access to data including VAERS (27)

CDC must work with parents and advocacy groups to rebuild trust and collaboration (27)

CDC must work with parents on more informed choice i.e. assent or dissent about benefits and risks as well as ability to delay immunizations vs. mandating vaccines (24)

There is bias and unequal review of all research around the issue of the alleged link between vaccines and ASD (Autism Spectrum Disorder) and other neuro-developmental disorders as well as chronic diseases and CDC must be willing to collaborate and work with those individuals with a different perspective and/or different research outcomes (10)

Collaborate more with health care providers, parents, advocacy groups, hospitals and others in educating and updating them about issues with immunizations (8)

CDC does extremely well in coordination/collaboration with the public, other federal government agencies and internationally (7)

Need much more collaboration of all agencies and groups involved in the production, manufacturing, administration and reporting of vaccines (6)

More education needed regarding the benefits of vaccines to the community and adverse events (5)

Work with those doctors and scientists who have documented an alleged link between vaccines and Autism Spectrum Disorder (2)

Allow physicians who practice complementary and alternative medicine to be involved in oversight of vaccine safety (2)

Collaborate with legislators (1)

***Objective 3: Determine the optimal organizational location for vaccine safety activities within the CDC to ensure scientific objectivity, transparency and oversight while at the same time ensuring that program priorities are appropriately established and are relevant to the immunization program and other stakeholder needs.***

Independent, no conflict of interest (especially pharmaceutical) with appropriate line of authority within CDC (31)

Must have objective researchers with no conflict of interest (especially with pharmaceutical industry) (18)

Goal is to protect the child first and foremost and must avoid any perception of conflict of interest, collusion with private companies, pharmaceutical companies who stand to profit, etc. Vaccine safety must be a priority (17)

Inherent conflict between promotion of vaccines and vaccine safety (11)

Include parent and advocacy groups in oversight of vaccine safety who have no conflict of interest (10)

Do not locate outside of CDC but avoid the perception of conflict (8)

Remember you are dealing with people and not statistics (6)

Locate outside of CDC in an independent agency. CDC has too much conflict. Vaccine safety activities needs to be completely independent (6)

No opinion about location (5)

This issue is of importance to national security and vaccine safety activities must be located very high within the organizational structure. (3)

Vaccine safety activities should be handled at the local health providers' office (1)

Vaccine safety should be done at the state level (1)

Transfer vaccine safety issues and funding to the FDA's center for Biologics Evaluation and Research (CBER) provided Congress changes FDA's mission to solely protecting the health and safety of the public without regard to the impact of that protection on the drug industry. (1)

Incorporate the "party model" used by the National Transportation Safety Board which offers the best of "separation and integration" recognizing that there are appropriate stakeholders that should be "party" to a safety investigation, but the leader of the team is seen as being independent and impartial. (1)

Remove the vaccine safety group from the National Immunization Program and place in another center such as the Epidemiology Program Office or the office of the Associate Director of Science. (1)

Concerned about potential threats to the privacy of this data, IOM's work on vaccine safety has also been very important and must CDC continue this collaboration. (1)

### **III. Additional comments:**

Take thimerosal/Hg/ and all other preservatives and additives such as aluminum out of the vaccines (63)

No need for so many vaccines. Vaccines are not safe; they are dangerous (36)

Believes there is a causal relationship between thimerosal/Hg and/or giving so many vaccines together in such a short time span in vaccines and autism (32)

There is a perception that CDC is too tied to the pharmaceutical industry and they have a great impact on policy decisions made in regards to immunizations. (28)

Look at genetic predisposition to VAEs (24)

Need to change the immunization schedule and allow more time between vaccines (23)

CDC has lost credibility and the trust of some groups and needs to rebuild it (23)

We are over vaccinating the children and not allowing them to develop natural immunity to disease (Children are being given vaccines too early in their development before their systems have had time to mature.) (17)

More research is needed to document the efficacy of the mass immunizations (14)

There are many concerns regarding the Hepatitis B vaccine (why are we giving it to children at 1 day of age) (13)

Must have ongoing review, revision and monitoring both internally and externally (10)

Need more research on the VAEs (6)

Many children have been found to be toxic with Hg after vaccination; CDC must study this issue (6)

Concerns about giving immunizations when child is ill and on antibiotics (5)

Get politics out of policy making and stick to the science (4)

Good science is not being utilized in tracking emerging and rare AE (4)

Give single dose vaccines (5)

Find the cause of adverse effects (4)

Delay all vaccines until age 3 at that time the brain is more fully developed (3)

Concerned about vaccine shortages and safety of supply (3)

Need to conduct double blind studies (3)

Audit and certify labs/manufacturing facilities that make vaccines (3)

Federal government needs to get out of the vaccine business. Abolish CDC and FDA and allow the free market to take over (2)

Need easier way to search the VAERS database (2)

Stop consulting with IOM (1)

Increase funding for vaccines (1)

Need complete culture change at CDC. Perception is that scientists are arrogant. (1)

Determine best practices for vaccine research (1)

Educate consumers about vaccine safety such as the steps taken to get vaccines approved (1)

Difficult to understand the objectives (1)

FDA must continue to have a critical in vaccine safety i.e. reviewing all pertinent data collected by CDC and from NIH funded research. (1)

CDC work with DHHS to remove ineffective and harmful vaccines from the marketplace and restrict new vaccines to those where a single vaccination with a 5 year, 10 year, or longer booster provides protection for 100% (not less than 95.5%) of the otherwise healthy persons who are vaccinated. (1)

CDC must be willing to look outside the box (1)